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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/290,049	04/12/1999	DANIEL J. SMITH	FDC98-01P2A	9419

21005 7590 02/21/2003

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/290,049

Applicant(s)

SMITH ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15October2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-28,31-38,41-48,51-58,61-68 and 71-78 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-28,31-38,41-48,51-58,61-68 and 71-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 15 October 2002, paper #26, is acknowledged.

Claims 29, 30, 39, 40, 49, 50, 59, 60, 69, 70, 79, and 80 have been canceled. Claims 20, 24, 31, 34, 41, 44, 51, 54, 61, 64, 71, and 74 have been amended.

2. Claims 12-14, 20-28, 31-38, 41-48, 51-58, 61-68, and 71-78 are pending. Claims 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (Office Action, 14 March 2000, paper #9).

3. Claims 20-28, 31-38, 41-48, 51-58, 61-68, and 71-78 are under consideration.

### **Rejections Moot/Withdrawn**

4. The rejection of claims 29, 30, 39, 40, 49, 50, 59, 60, 69, 70, 79, and 80 under 35 U.S.C. 112, second paragraph, as being indefinite for the positions of the claimed amino acids, is moot in light of the cancellation of the claims.

5. The rejection of claims 29, 30, 39, 40, 49, 50, 59, 60, 69, 70, 79, and 80 under 35 U.S.C. 112, first paragraph, scope of enablement for compositions which induce immune responses resulting in the reduction of the colonization or accumulation of mutans streptococcal strain in a mammal or for vaccine compositions, is moot in light of the cancellation of the claims.

6. The rejection of claims 29, 30, 39, 40, 49, 50, 59, 60, 69, 70, 79, and 80 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for the limitation "the vaccines" is moot in light of the cancellation of the claims.

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7. The rejection of claims 20, 21, and 22 under 35 U.S.C. 102(b) as being anticipated by Kuramitsu et al (*Archives of Oral Biology*, 23(8):691-696, 1978) is withdrawn.

Applicants argue that the claim amendments now state that the composition does not comprise intact *S. mutans* glucosyltransferase-B protein and that Kuramitsu et al do not teach nor suggest composition comprising subunits of *S. mutans* glucosyltransferase-B protein.

The examiner has considered applicants' argument, and finds it persuasive.

#### **Rejections Maintained**

8. The provisional rejection of claims 21, 22, 25, 32, 35, 42, 45, 52, 55, 62, 65, 72, and 75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 14, and 15 of copending Application No. 09/562,328, is maintained.

Applicants request that a reply to the merits of this provisional rejection be postponed until either copending application no. 09/562,328 issues as a patent or until the rejection is the only rejection remaining in the instant application.

9. The rejection of claims 20, 23, 24, 26, 27, 28, 31, 33, 34, 36, 37, 38, 41, 43, 44, 46, 47, 48, 51, 53, 54, 56, 57, 58, 61, 63, 64, 66, 67, 68, 71, 73, 74, 76, 77, and 78 under 35 U.S.C. 112, second paragraph, as being indefinite for the positions of the claimed amino acids, is maintained for reasons of record.

Applicants argue that the claim amendments obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. The only requirement for the  $\geq 1$  peptide is that it comprises one of the 5 listed amino acids and be of

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sufficient length to raise an immune response. However, it remains unclear whether the peptide begins or ends with the particular amino acid or if the particular amino acid occurs somewhere in the middle of the peptide. Also, what is “sufficient length”?

The instant specification and sequence listings do not contain the specific full length amino sequence of the *S. mutans* glucosyltransferase-B protein to which the claims refer in order to designate the particular amino acids. Applicants’ response states that the specification clearly indicates that the sequences utilized as a basis for the numbering of the recited amino acids are the protein sequences provided in the five references listed at the end of Table 1. However, each of the five references display different sequences, some from a different organism, with different numbering schemes. Therefore, without a particular sequence starting point/reference, the number designations in the instant claims is indefinite.

10. The rejection of claims 26, 27, 36, 37, 46, 47, 56, 57, 66, 67, 76, and 77 under 35 U.S.C. 112, first paragraph, scope of enablement for constructs further comprising portion of pathogens, is maintained.

Applicants argue that the teachings of the specification enable the skilled person to practice the invention without undue experimentation.

The examiner has considered applicants’ argument, but does not find it persuasive for the reasons put forth in the original rejection.

### **Conclusion**

11. Claims 20-28, 31-38, 41-48, 51-58, 61-68, and 71-78 are finally rejected.

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**12. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**13.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

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February 20, 2003



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER